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| 10/518,822 | 01/13/2005 | Mitsuru Horiba | ADACHI P265US | 9877 |
| 20210 7590 06/17/2009 DAVIS & BUJOLD, P.L.L.C. 112 PLEASANT STREET CONCORD, NH 03301 | | | | |
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| PATEL, SHEFALI DILIP | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/518,822

Applicant(s)

HORIBA ET AL.

Examiner

SHEFALI D. PATEL

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-9 and 11-18 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 21, 2009, has been entered.

Acknowledgments

2. In the after final response, filed on April 27, 2009, Applicant amended claims 6, 9, 10, 11, 16, and 18.
3. In the final rejection of February 24, 2009, Examiner objected to claims 9, 10, 16, and 18 for minor informalities. Applicant amended claims 9, 10, 16, and 18. Objections are withdrawn.
4. Currently, claims 6-18 are under examination.

Response to Arguments

5. Applicant's arguments with respect to claims 6-18 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter not previously presented in the claims into independent claims 6 and 11.

Claim Objections

6. Claim 10 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

In regards to claim 10, claim 10 is improper because it is a multiple dependent claim that depends on a previous multiple dependent claim 9.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In regards to claims 6 and 11, the limitation that the outer tube is "sufficiently small in size so as to be inserted into a blood vessel" appears to be new matter as it is unclear where in the specification it is stated that the outer tube must be "sufficiently small".

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 11, the claim recites the limitation “the target region”. There is insufficient antecedent basis for this limitation in the claim, as “a target region” has not been previously introduced in the claim.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 6-9, 11, 12, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al (US 5,536,251), and further in view of Kratsch et al (US 5,478,350).

In regards to claim 6, Evard et al teaches a catheter (Figures 5A-6D, device [110]) comprising:

- a. an outer tube (outer shaft [66])
- b. a first inner tube (inner shaft [72]) located within the outer tube [66] and containing a forceps mechanism (jaw extensions [78][80] with lever [94])
- c. a second inner tube (inner sleeve [112]) also located within the outer tube [66] containing an injection mechanism (delivery tube [120] with needle [124])

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- d. the forceps mechanism having a first handling portion [94] at the proximate end (Figure 5A) and a grasping portion (jaws [82][84]) at the distal end (Figure 5B), the grasping portion being configured to open and close in conjunction with manipulation at the first handling portion, and being capable of holding the target region accessed by the catheter (column 8, lines 46-51)(column 9, lines 7-10)
- e. the injection mechanism having a second handling portion (actuation button [140]) at the proximate end, and an injection needle [124] at the distal end, the injection needle being configured to be moved forward into a position to so as to protrude from the distal end (Figures 6B-6C), and to be moved back into a retracted position stored inside of the distal end (Figure 6D), and the injection mechanism being capable of puncturing the target region with the injection needle and injecting injectant into the target region (column 10, lines 8-13)

Evard et al does not teach that the outer tube [66] is sufficiently small in size so as to be inserted into a blood vessel, since Evard et al only teaches the insertion of the outer tube into the chest wall and into the thoracic cavity through an intercostal space between two adjacent ribs (column 13, lines 42-46). However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the outer tube of Evard et al to be smaller in size for insertion into a blood vessel, since it has been held that merely changing the size or proportion of a device is not sufficient to patentably distinguish over the prior art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). A person having ordinary skill in the art at the time the invention was made would know how to scale down the outer

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tube of the catheter of Evard et al for the purposes of providing treatment to a blood vessel.

In further regards to claim 6, Evard et al does not teach an operating linkage constrained within the first inner tube in a closed position. Kratsch et al teaches a forceps mechanism (Figures 15-17), wherein an operating linkage (hook [116] with curved surface [106]) of a forceps mechanism (end effectors [58][59]) is constrained within a tube (sleeve [64]) in a closed position (Figure 16). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the catheter of Evard et al, with an operating linkage that is constrained within the first inner tube in a closed position, as taught by Kratsch et al, as the operating linkage will determine the rate at which the grasping portion closes and the rate of change in the rate at which the grasping portion closes. By proper arrangement of the operating linkage within the inner tube, the grasping portion can be arranged with constant linear movement of the handling portion to accelerate, decelerate, or vary speeds in the closing motion (column 8, lines 62-67 to column 9, lines 1-16).

In regards to claim 7, in a modified catheter of Evard et al and Kratsch et al, Evard et al teaches that the forceps mechanism [78][80][94] is configured to bias the grasping portion [82][84] toward a direction to close the grasping portion with force of a spring (spring, not shown) (column 8, lines 52-54)(column 9, lines 7-10).

In regards to claim 8, in a modified catheter of Evard et al and Kratsch et al, the current embodiment of Evard et al (Figures 5A-6D) does not teach that the forceps mechanism comprises a lock device that prevents the grasping portion opening and closing. Evard et al teaches another embodiment (Figures 1-2B) in which a forceps

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mechanism (jaws [30][32] with actuator [36]) comprises a lock device (notched extensions [42]) that prevents a grasping portion opening and closing (column 7, lines 37-46). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the modified catheter of Evard et al (Figures 5A-6D) and Kratsch et al, with a lock device, as taught by Evard et al (Figures 1-2B), as the lock device will provide ratcheted locking of the forceps mechanism in order to maintain the grasping portion in a closed position in order to avoid unnecessary opening and actuation of the grasping portion (column 7, lines 42-46).

In regards to claim 9, in a modified catheter of Evard et al and Kratsch et al, Evard et al teaches that the injection mechanism is configured to bias the injection needle [124] toward a direction to move back the injection needle with the force of a spring (spring [164]) (column 10, lines 14-27).

In regards to claim 11, Evard et al teaches a catheter (Figures 5A-6D, device [110]) comprising:

- a. an outer tube (outer shaft [66])
- b. a first inner tube (inner shaft [72]) located within the outer tube [66] and containing a forceps mechanism (jaw extensions [78][80] with lever [94]) having a first handling portion [94] at the proximate end (Figure 5A) and a grasping portion (jaws [82][84]) at the distal end (Figure 5B), and being capable of holding the target region accessed by the catheter (column 8, lines 46-51)(column 9, lines 7-10)

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c. a second inner tube (inner sleeve [112]) located within the outer tube [66] containing an injection mechanism (delivery tube [120] with needle [124]) having a second handling portion (actuation button [140]) at the proximate end and an injection needle [124] at the distal end, the injection needle being configured to be moved forward into a position to so as to protrude from the distal end (Figures 6B-6C), and to be moved back into a retracted position stored inside of the distal end (Figure 6D), and the injection mechanism being capable of puncturing the target region with the injection needle and injecting injectant into the target region (column 10, lines 8-13)

Evard et al does not teach that the outer tube [66] is sufficiently small in size so as to be inserted into a blood vessel, since Evard et al only teaches the insertion of the outer tube into the chest wall and into the thoracic cavity through an intercostal space between two adjacent ribs (column 13, lines 42-46). However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the outer tube of Evard et al to be smaller in size for insertion into a blood vessel, since it has been held that merely changing the size or proportion of a device is not sufficient to patentably distinguish over the prior art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976). A person having ordinary skill in the art at the time the invention was made would know how to scale down the outer tube of the catheter of Evard et al for the purposes of providing treatment to a blood vessel.

In further regards to claim 11, Evard et al does not teach an operating linkage constrained within the first inner tube in a closed position. Kratsch et al teaches a forceps

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mechanism (Figures 15-17), wherein an operating linkage (hook [116] with curved surface [106]) of a forceps mechanism (end effectors [58][59]) is constrained within a tube (sleeve [64]) in a closed position (Figure 16). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the catheter of Evard et al, with an operating linkage that is constrained within the first inner tube in a closed position, as taught by Kratsch et al, as the operating linkage will determine the rate at which the grasping portion closes and the rate of change in the rate at which the grasping portion closes. By proper arrangement of the operating linkage within the inner tube, the grasping portion can be arranged with constant linear movement of the handling portion to accelerate, decelerate, or vary speeds in the closing motion (column 8, lines 62-67 to column 9, lines 1-16).

In regards to claim 12, in a modified catheter of Evard et al and Kratsch et al, Evard et al teaches a spring (spring, not shown) having a spring force wherein the spring force maintains the forceps mechanism [78][80][94] in the closed state (column 8, lines 52-54)(column 9, lines 7-10).

In regards to claim 16, in a modified catheter of Evard et al and Kratsch et al, Evard et al teaches a deflectable spring (spring [164]) which maintains the needle [124] of the injection mechanism in a retracted state within the second inner tube [112] (column 10, lines 14-27).

13. Claims 13-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al and Kratsch et al, as applied to claims 11 and 12 above, and further in view of Clement et al (US 5,350,384).

In regards to claim 13, in a modified catheter of Evard et al and Kratsch et al, Evard et al teaches that the spring force is overcome by an operator influencing the first handling portion [94] (column 8, lines 52-54); however, Evard et al is silent about whether the spring is compressed to move the grasping portion [82][84] to the open state. Clement et al teaches a forceps mechanism (Figures 1-6B) wherein a spring (compression spring [44]) is compressed to move a grasping portion (jaws [32]) to an open state (Figure 6B) (column 4, lines 5-10). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the spring of the forceps mechanism, of the modified catheter of Evard et al and Kratsch et al, to compress to move the grasping portion to an open state, as taught by Clement et al, as a preferential obvious design choice to the user, as compression of the spring will provide a suitable and efficient means for moving the grasping portion to the open state (column 4, lines 5-10).

In regards to claim 14, in a modified catheter of Evard et al, Kratsch et al, and Clement et al, Evard et al does not teach a linkage of the grasping portion [82][84]. Kratsch et al teaches an operating linkage (hook [116] with curved surface [106]) of a forceps mechanism (end effectors [58][59]) that is constrained within a tube (sleeve [64]) in a closed position (Figure 16) and is displaced outside of the tube to facilitate a complete lateral expansion of the linkage and a fully open position of the grasping portion [58][59] (Figure 15). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the catheter of Evard et al, with an operating linkage that is constrained within the first inner tube in a closed position and displaced outside of the first inner tube in an open

position, as taught by Kratsch et al, as the operating linkage will determine the rate at which the grasping portion closes and the rate of change in the rate at which the grasping portion closes. By proper arrangement of the operating linkage within the inner tube, the grasping portion can be arranged with constant linear movement of the handling portion to accelerate, decelerate, or vary speeds in the closing motion (column 8, lines 62-67 to column 9, lines 1-16).

In regards to claim 15, in a modified catheter of Evard et al, Kratsch et al, and Clement et al, the current embodiment of Evard et al (Figures 5A-6D) does not teach that the forceps mechanism comprises a lock device that prevents the grasping portion opening and closing. Evard et al teaches another embodiment (Figures 1-2B) in which a forceps mechanism (jaws [30][32] with actuator [36]) comprises a lock device (notched extensions [42]) that prevents a grasping portion opening and closing (column 7, lines 37-46). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the forceps mechanism, of the modified catheter of Evard et al (Figures 5A-6D), Kratsch et al, and Clement et al, with a lock device, as taught by Evard et al (Figures 1-2B), as the lock device will provide ratcheted locking of the forceps mechanism in order to maintain the grasping portion in a closed position in order to avoid unnecessary opening and actuation of the grasping portion (column 7, lines 42-46).

In regards to claim 18, in a modified catheter of Evard et al and Kratsch et al, neither Evard et al nor Kratsch et al teaches that the linkage comprises a four-bar mechanism. Clement et al teaches a forceps mechanism (Figures 1-6B) wherein a linkage comprises a four-bar mechanism (jaws [32] and spreader links [38]) (Figures 6A-6B). It

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would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the linkage, of the forceps mechanism of the modified catheter of Evard et al and Kratsch et al, with a four-bar mechanism, as taught by Clement et al, as the four-bar mechanism will allow the grasping portion to laterally spread in the open position for clamping around a patient's body portion and laterally compress in the closed position for storage (column 3, lines 59-68).

14. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al and Kratsch et al, as applied to claim 16 above, and further in view of Haughton et al (US 5,376,075).

In regards to claim 17, in a modified catheter of Evard et al and Kratsch et al, Evard et al does not teach a piston and a cylinder for overcoming a bias of the deflectable spring [164] that is configured to retract the needle [124] and a locking device that is actuatable to maintain the needle in a desired position. Haughton et al teaches an injection mechanism (Figures 6-10), wherein a spring (spring [148]) biases an injection needle (trocar [130]) of the injection mechanism toward a direction to move back the injection needle (Figures 8-9). Haughton et al also teaches that the injection mechanism further comprises a piston (stud [146]) and a cylinder (hub [142]) for overcoming the bias of the spring [148] with a locking device (stud [146] in slots [150][152]) for maintaining the needle in the extended position. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the injection mechanism, of the modified catheter of Evard et al and Kratsch et al, with a piston, cylinder, and locking device, as taught by Haughton et al, as the piston, cylinder, and

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locking device will retain the needle in the extended position during insertion of the catheter into a blood vessel, and the spring will urge the needle inwardly away from its extended position in order to enclose the sharpened end of the needle after use (Abstract)(column 6, lines 39-59).

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Grabek et al (US 6,231,518), Malecki et al (US 6,368,340), and Malecki et al (US 5,626,607).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/

Examiner, Art Unit 3767

06/15/2009

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767